

DRAFT January 3, 2002 Meeting Summary for February 25, 2002 GTF Meeting
January 3, 2002 Genetics Task Force Meeting Summary

Purpose

This document summarizes the previous GTF meeting. It presents some of the broader questions addressed at the meeting and proposes some answers to those questions. The staff hopes that this summary puts the diverse array of information presented at the meeting into a useful context for the GTF members and helps to define the direction and progress of the GTF meetings.

Meeting Overview

The Genetics Task Force (GTF) heard presentations on 1) the basic science of genetics, 2) previous legislative efforts in Washington State, and 3) existing federal and state laws and Institutional Review Board policies that govern and protect privacy in Washington state. In addition, the Genetics Task Force heard comments from key Washington State legislators regarding their perspectives on genetics privacy and anti-discrimination legislation. Information presented at the meeting addressed several fundamental questions facing the task force and introduced new ideas and questions to be answered over the course of the Genetics Task Force's tenure.

Questions Answered

The following questions were answered in the course of the first GTF meeting.

1. *What does current technology allow researchers, physicians and others to glean from DNA?*

Current technology provides physicians, researchers, and others the ability to detect genetic mutations and variations in an individual's DNA. Mutations or variations in DNA may reveal information about disease susceptibility/resistance and ability to metabolize pharmaceutical drugs and environmental elements. Relatively few mutations are known to cause specific diseases; for example Huntington disease, cystic fibrosis, phenylketonuria (PKU), sickle cell anemia, Duchenne's muscular dystrophy and hemophilia are each caused by single-gene mutations. Single-gene disorders are rare. More common are diseases that result from complex gene-gene and gene-environment interactions in which a genetic mutation is associated with an increased risk of disease but does not determine with absolute certainty that the disease will manifest. Examples of complex diseases include asthma, cardiovascular disease, breast cancer, colon cancer, and the most common types of diabetes.

Physicians, researchers and others can also learn information about an individual's relatives from the individual's DNA. For example, information about the risk of bearing affected children or of having a living relative who carries a specific mutation can be gleaned from a genetic test. This information is usually presented in terms of risk and probabilities and is not definitive.

DNA can also serve as a unique identifier for an individual.

2. *What are some of the potential ethical, legal, and social issues related to privacy and discrimination introduced by genetic technology?*

Ethical, legal and social issues related to genomics include:

- Discrimination/stigmatization. Genetic information can lead to the differential treatment of individuals. One example is newborn screening for phenylketonuria (PKU) in which newborns identified as having the disorder are selectively treated in order to prevent the onset of disabling mental retardation. A second example is the use of genetic information about a disease susceptibility to preclude employment in which an environmental exposure would increase the likelihood that the disease develops. A third example is a situation in which an individual who seeks health and/or life insurance is assigned a higher premium based on the fact that he had a genetic test in the past that revealed a mutation suggestive of an increased risk for a disease. These examples illustrate the potential to use genetic information to beneficially discriminate against an individual or to adversely discriminate against an individual. In the first example, genetic information is used to prevent the onset of a disabling condition. In the second example, non-definitive genetic information is used to adversely discriminate against a person under the assumption that it is for the person's benefit. The third example illustrates the potential power of genetic information to influence health insurance underwriting. The availability of genetic information introduces the following questions: 1) What degree of scientific evidence is sufficient in order to use genetic information? 2) When is it appropriate to use genetic information? 3) Who decides when the information is of benefit or harm?
- Affordability/accessibility. Access to health care in the U.S. is conditional, based not on citizenship, but rather on certain social circumstances such as poverty, age and employment status. Does the potential to use genetic information to predict, prevent and treat genetic diseases warrant a change in how genetic services are provided and accessed? If genetic tests are mandated and/or universally available, should treatment and follow up procedures also be compulsory?
- Duty to disclose. Physicians may be faced with the dilemma of whether or not to reveal information about a patient to members of the patient's family who may also be at risk of developing a genetic disease. What legal guidance do physician's need to solve this dilemma?
- Research. It is generally accepted that autonomous persons should be informed about and freely consent to medical and research procedures. What specific processes, in excess of those that already exist, should be in place to ensure that research subjects are fully informed about and protected from the risks involved in genetic research?

3. *What is the charge to the GTF?*

The legislative mandate states that the GTF review available information on the potential risks and benefits to public and personal health and safety, and to individual privacy, of emerging technologies involving DNA. The GTF must consider information provided to it on

- a) incidence of discriminatory actions based upon genetic information
- b) strategies to safeguard civil rights and privacy related to genetic information
- c) remedies to compensate individuals for inappropriate use of the genetic information, and
- d) incentives for further research and development on the use of DNA to promote public health, safety and welfare.

The GTF must report findings and any recommendations to appropriate legislative committees by October 2002.

The GTF contemplated broadening the scope of work, however time and resource constraints led the GTF to conclude that the scope of work will remain as approved by the Board of Health in the Work Plan.

4. What previously introduced legislation addressed privacy and discrimination issues?

Number	Year	Title	Description
SB5298	1998		This bill protects genetic information from health insurance discrimination, and defines genetic information as information about genes, gene products, or inherited characteristics
SB6663	1998		This bill prohibits insurer discrimination in coverage or benefits on the basis of genetic information, and employer discrimination on the basis of genetic information. Additionally, it protects the right of an individual to refuse to disclose genetic information, and it creates a cause of action for violation of the provision. Genetic information is defined as information about inherited characteristics
SB5111	1999	Health Insurance Discrimination	This version of the bill prohibits health insurance discrimination on the basis of genetic information. It declares that a health carrier may not deny or cancel health plan coverage or vary the premiums, terms, or conditions for coverage, for an individual or a family member of an individual either 1) on the basis of genetic information, or 2) because the individual or family member of an individual has requested or received genetic services. It additionally prevents a health carrier from requesting disclosure of individual's genetic information, and it also prevents the health carrier from disclosing any genetic information about an individual without his consent.
ESSB5111	1999	Health Insurance Discrimination	This bill is very similar to SB 5111 described above. It adds three limited situations in which a health carrier may disclose a patient's genetic information: research, internal use for family genetic counseling, and newborn screening authorized by 70.83 RCW.
HB2861	2000	Health Care Information Definition	This bill modifies the definition of "health care information" to explicitly include "a patient's deoxyribonucleic acid and identified sequence of chemical base pairs".
SB6284	2000	Protection of DNA Information	This bill, as originally introduced, protects DNA identification information, specifically data collected during criminal investigations of suspects who were not convicted, or juvenile victims or offenders. As substituted in Jan., 2000 this bill sets up a DNA commission to evaluate issues relating to use and protection of DNA information.
SB6326	2000	Insurance Transactions	This bill prevents a person's DNA from being screened for any insurance transaction.
SB6327	2000	Genetic Discrimination	This bill prevents genetic discrimination using "information obtained from interpreting the sequence of chemical base pairs in a person's deoxyribonucleic acid". It amends RCW 49.60.
SB6340	2000	Civil Action	This bill creates a civil action for improperly obtaining a persons DNA.
SB6341	2000	Informed Consent	This provision requires informed consent before obtaining a person's DNA. It specifies requirements for informed consent, and it lists circumstances in which informed consent is not needed.
ESSB6395	2000	DNA Technology Issues Commission	In addition to establishing a commission, this bill prevents screening of a person's DNA in an insurance transaction, it prevents discrimination regarding DNA screening in employment, it requires informed consent before isolating DNA for identification purposes, and it extends the commission for five years.
SB5207	2001	Individually Identifiable DNA Testing	This bill relates to individually identifiable DNA testing. It redefines health care information to include "genetic test information from a person's isolated DNA and a person's DNA when obtained at the request of a health care provider or health care facility." The bill also sets up a commission to report by July 1, 2002 on issues including use and misuse of DNA and genetic information, genetic privacy, and genetic discrimination.
SB5282	2001	DNA Use in Insurance Transactions	This bill prevents insurers from "screening" an individual's DNA. In this regard, it adds a new section to chapter 48.01 RCW.
SB5283	2001	Discriminatory Use of DNA in Employment Matters	This bill expands on the general right to be free from discrimination in employment on the basis of "race, ...sex...[or] disability", by adding a specific right to prevent employers from screening a person's DNA. It amends RCW 49.60.030.
SB5284	2001	DNA Informed Consent	This bill requires informed consent prior to isolating DNA in a form that identifies an individual for the purposes of genetic testing. Informed consent must include specific elements, and the bill lists specific circumstances in which informed consent under this section is not required.
SB5665	2001	Genetic Information	This bill declares that each person has a fundamental privacy interest in his or her genetic information. It also protects an individual's right to choose or refuse to release their genetic information.

5. *How and where is 'genetic information' defined in existing state and federal law?*

Few state and federal laws explicitly define 'genetic information'. Definitions for terms such as 'health information' or 'health care information' are much more common. Please refer to the attached glossary or number 6 below for specific definitions for these terms.

Genetic information is specifically referred to in state and federal policies regarding portability of health insurance. Both HIPAA and the Washington State Office of the Insurance Commissioner Rules in reference to a pre-existing condition state that "genetic information shall not be treated as a health condition in the absence of a diagnosis of the condition related to such information." (WAC 284-43-720 Guaranteed issue and restrictions on the denial, exclusion, or limitation of health benefits for preexisting conditions) HIPAA applies only to group health insurance plans or health insurers that offer group health insurance (usually those with more than 50 members). The state OIC Rules apply to all health insurers governed by state law. Federal law governs self-insurers.

6. *How do health information and genetic information interact within the provisions of HIPAA? How do health information and genetic information interact in state law?*

HIPAA - The definition of "Health Information" is "any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual or the provisions of health care to an individual or the past, present, or future payment for the provision of health care to an individual." The NCSL states "this definition includes currently manifested diseases of genetic origin as well as genetic information, since such information "relates to" a possible future medical condition."

Washington State Uniform Health Care Information Act – Defines "Health Care Information" as "any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and is directly related to the patient's health care." "Health Care" is defined as "any care, service or procedure provided by a health care provider." Lawmakers attempted to make it explicitly clear that this definition includes information obtained from DNA. For example, HB 2861 sought to amend the definition of "Health Care Information" in the Uniform Health Care Information Act by adding the following statement, "The term includes genetic test information in a person's DNA and a person's DNA ". HB 2861 did not pass.

7. *What protection do current federal and state laws/policies provide with respect to genetic information?*

Federal laws protecting genetic information include: HIPAA, ADA, and the Civil Rights Act. State laws and policies applicable to genetic information include UHCIA, the Washington State Patient's Bill of Rights, and the Governor's Executive Order on Privacy.

Federal

HIPAA – HIPAA protects health information by granting the patient specific control over the release and use of the information. The release of information related to health care treatment, payment and health care operations, termed "routine uses," requires consent and providers are not required to provide care if the patient does not consent to the release of

information for these purposes (NCSL). Disclosures for other purposes require patient authorization but care cannot be denied in the absence of such consent (NCSL).

HIPAA applies to health care information in all mediums (oral, written, electronic, etc). HIPAA applies to health care providers and insurers. HIPAA does not protect health care information outside of the health care system and its business partners; information is protected from disclosure to entities outside the health care system, but once it has left a covered entity, it is no longer protected by HIPAA and the new holder is not required to maintain confidentiality or get consent before further disclosing the information. However, other laws may still protect the information. Separate privacy mandates exist at both the state and national level that protect inmates, school records, public health, mental health, and other specific areas. HIPAA does not apply to individual or small group insurers (those with fewer than 50 individuals). For example, under the provisions in HIPAA, an individual who has an insurance policy that is not subject to HIPAA regulations can visit a physician and pay out of pocket for services provided from that physician in order to avoid disclosure of information to his insurance company. In this case, the physician must comply with the standards of HIPAA and is not permitted to disclose information to the insurance company or any other party without the patient's consent. However, if the patient wishes to bill his insurance company for the service, he must consent to the release of the information for payment purposes or the physician can deny care. Once the insurance company in this example obtains the information, it is no longer protected by HIPAA. Therefore, the insurer could potentially release the information to an employer or other party without the patient's consent. The Washington state Patient's Bill of Rights prohibits this type of disclosure as it makes all health insurers governed by state law subject to the provisions of the Uniform Health Care Information Act.

Public health, research, law enforcement, and other uses required by law are also exempt from specific consent requirements; these entities generally have their own privacy and confidentiality restrictions. HIPAA imposes civil and criminal penalties for violations however, currently no agencies are required to monitor compliance but enforcement regulations are forthcoming. For the present time, complaints must be reported to Health and Human Services (HHS) at which time HHS will investigate.

HIPAA does not prevent entities (health care providers, insurers, mortgage lenders, employers, or others) from requesting genetic information from an individual or from denying or altering services because of a refusal to provide genetic information. Requests for genetic information by employers may be regulated by the ADA, see below.

ADA – The Equal Employment Opportunities Commission (EEOC) interprets the American's with Disabilities Act as encompassing genetic disorders. The EEOC considers that employers who discriminate against employees on the basis of predictive genetic tests "regard" the employees as having a disabling impairment and are therefore acting in violation of the ADA (EEOC Compliance Manual, secs. 902-45, March 14, 1995). This argument has not been tested in court and is only an interpretation of the ADA.

Civil Rights Act – "Title VII of the Civil Rights Act of 1964 may incidentally provide protection against some forms of genetic discrimination, because genetic discrimination may have a disparate impact based on race, color, religion, sex, or national origin. For example, an employer may violate Title VII by engaging in discrimination based on a genetic trait that disproportionately impacts a particular protected group, such as sickle cell disease

(individuals of African descent) or Tay-Sachs disease (Ashkenazi Jews). Because genetic screening is a facially neutral policy, claims under Title VII would most likely be brought on a disparate impact theory. Although some courts have implied that employment decisions based on genetic profiles associated with a particular protected class would violate Title VII, thus far, no successful lawsuits have been brought under this theory. Also, many, if not most, genetically related diseases and disorders do not disproportionately affect one of Title VII's protected classes; thus, Title VII does not provide comprehensive protection against genetic discrimination in employment.” (Miller, Stephen. Genetic Discrimination in the Workplace. *Journal of Law, Medicine, and Ethics*. 26(1998):187-97).

State

UHCIA – Washington State Uniform Health Care Information Act applies to all licensed health care providers and facilities in the state. UHCIA requires a patient’s written authorization for the disclosure of health care information. Patient’s can bring civil suits against violators and may be awarded damages.

Washington State Patient’s Bill of Rights - Applies to insurers and third party payers; makes insurers subject to provisions of the UHCIA.

Governor’s Executive Order on Privacy 00-03 – Limits the collection and retention of personal information by state agencies and contractors. Places entities that are exempt from HIPAA under similar requirements. Encompasses all readily identifiable information. Penalties apply to state employees and include dismissal.

8. *What are some of the reasons previously proposed Washington state genetic privacy and anti-discrimination legislation did not pass?*

Some reasons expressed by Senator Franklin and Representative O’Brien include:

- a) Concerns that the legislation would limit the ability of researchers to conduct necessary studies of human genetics
- b) Long-term consequences were not considered when the legislation was drafted

9. *Where is biological material (potential sources of DNA) collected and stored? How are samples and data protected?*

There are many places where biological material is stored. The GTF heard about the State’s Newborn Screening Program (NBS) as an example of a public archive. Private companies, hospitals, and researchers also store biological material.

The NBS samples and associated data are protected at various levels. Regulations and internal policies protecting the data and samples include:

- a) Confidentiality agreements signed by DOH personnel and contractors
- b) Institutional Review Board review of research requests
- c) Reports generated are limited to quality control reports
- d) Parental or patient consent is required for most types of disclosure
- e) Data are kept in secure locations and access is limited

Private institutions are not regulated by a universal regulation regarding storage, use and access. Researchers receiving federal funding are required to abide by the Federal Common

Rule for Protection of Human Research Subjects (45CFR46). Privately funded research is not subject to this requirement.

10. What precedents have been set in court cases tried on the basis of the Washington State Uniform Health Care Information Act with respect to genetic information?

No cases regarding genetic privacy violations have been tried in WA.

11. Have there been cases involving claims of genetic discrimination tried in Washington state courts?

No.

12. How are research subjects protected from misuse of their genetic information?

Federally funded research must comply with the Federal Common Rule for Protection of Human Research Subjects (45CFR46). Research institutions submit research proposals to Institutional Review Boards (IRB) for approval. IRBs confirm that proposed research complies with federal and local laws and policies such as the Common Rule, Title I of the American's with Disabilities Act, HIPAA, RCW 70.02 (UHCIA), and RCW 42.48.040 (Disclosure by Researchers).

Privately funded research is not subject to federal regulations.

Questions Remaining (many of these will be topics of discussion at future meetings)

1. What laws define the types of genetic information insurance companies can request and how they can use the information? (February 25, 2002 meeting)
2. What laws define the types of genetic information employers can request and how they can use the information? (February 25, 2002 meeting)
3. How have research efforts in other states been affected by genetics privacy and anti-discrimination legislation? (February 25, 2002 meeting)
4. What evidence exists regarding genetic discrimination and/or privacy violations in Washington State? (February 25, 2002 meeting)
5. Do existing state laws address the use of pre-existing conditions for insurance coverage? If so, what does the law say about genetic testing and genetic discrimination and who does/doesn't it apply to? (February 25, 2002 meeting)
6. What are the concerns of academic and private researchers with respect to access to and use of DNA? (April 12, 2002 meeting)
7. What are the future directions and development plans for the bio-tech industry in WA? (April 12, 2002 meeting)
8. What, if any, problems have legislation in other states created for agencies, patients, physicians, insurance companies, etc? (February 25, 2002 meeting)
9. What are appropriate and reasonable incentives to stimulate genetics research and development? (April 12, 2002 meeting)
10. Do existing state/federal laws protect against genetic discrimination in employment? (February 25, 2002 meeting)
11. Have there been cases involving claims of genetic discrimination tried in Washington state courts? (February 25, 2002 meeting)
12. How should legislation in WA define DNA, genetic information, etc...?